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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
07/158,652	02/22/1988	MARC ALIZON	PAST-010-A	3369

7590 05/02/2003

FINNEGAN, HENDERSON, FARABOW,  
GARRETT AND DUNNER  
1300 I STREET, N.W.  
WASHINGTON, DC 200053315

EXAMINER
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FREDMAN, JEFFREY NORMAN

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 05/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

07/158,652

Applicant(s)

ALIZON ET AL.

Examiner

Jeffrey Fredman

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 133-141 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 133-141 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Status*

1. Claims 1-132 were cancelled
2. Claims 133-141 are pending.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 133-141 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a ``representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.)

Claims 131-141 is drawn to any complete HIV LTR, with or without appended sequence. This claim encompasses an enormous genus of nucleic acids which are

different from the single HIV LTR sequence that is disclosed in the specification. The genus includes variants for which no written description is provided in the specification. Thus, applicant has express possession of only one particular HIV LTR sequence in a genus which comprises hundreds of millions of different possibilities. Here, no common element or attributes of the sequences are disclosed, not even the presence of certain domains. No structural limitations or requirements which provide guidance on the identification of sequences which are necessary to function as an HIV LTR are provided.

It is noted in the recently decided case The Regents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997) decision by the CAFC that

"A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See *Fiers*, 984 F.2d at 1169- 71, 25 USPQ2d at 1605- 06 (discussing *Amgen*). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. "

In the current situation, the definition of the HIV LTR in claims 133-141 lacks any specific structure. This is precisely the situation of naming a type of material which is

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generally known to likely exist, but except for the one sequence disclosed, fails to provide descriptive support for the generic claim to any complete HIV LTR.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

"...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

The current situation is a definition of the compound solely by its functional utility, as an HIV LTR, without any definition of the particular sequences claimed.

In the instant application, certain specific SEQ ID NOs are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

"...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any nucleic acids other than those expressly disclosed which comprise complete HIV LTR sequences. Therefore, the claims fail to meet the written description requirement by encompassing sequences which are not described in the specification.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 133-141 are rejected under 35 U.S.C. 102(e) as being anticipated by Chang et al (U.S. Patent 6,001,977).

Chang teaches nucleic acid probes of HIV-1 sequence selected from the HIV sequence (column 9, lines 25-62 and column 10, line 65 to column 11, line 32),

where the specific sequence is disclosed as SEQ ID NO: 4, for example (columns 19-28).

The alignment of the Query HIV sequences of Chang and the subject sequences of the present application in the region between nucleotides 5670 and 8132 are presented below.

```
Query:      aaagagcaga 5569
            |||||
Sbjct:      aaagagcaga 5755
env      1      K E Q
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Query: 5570 agacagtggcaatgagagtgaaggagaaatatcagcacttgtggagatgggggtggagat 5629  
|||||

Sbjct: 5756 agacagtggcaatgagagtgaaggagaaatatcagcacttgtggagatgggggtggaaat 5815  
env 4 K T V A M R V K E K Y Q H L W R W G W K

Query: 5630 ggggcacccatgctccttgggatgttgatgatctgtagtgtctacagaaaaattgtgggtca 5689  
|||||

Sbjct: 5816 ggggcacccatgctccttgggatattgatgatctgtagtgtctacagaaaaattgtgggtca 5875  
env 24 W G T M L L G I L M I C S A T E K L W V

Query: 5690 cagtctattatggggtacctgtgtggaaggaagcaaccaccactctattttgtgcatcag 5749  
|||||

Sbjct: 5876 cagtctattatggggtacctgtgtggaaggaagcaaccaccactctattttgtgcatcag 5935  
env 44 T V Y Y G V P V W K E A T T T L F C A S

Query: 5750 atgctaaagcatatgatacagaggtacataatgtttgggccacacatgcctgtgtaccca 5809  
|||||

Sbjct: 5936 atgctaaagcatatgatacagaggtacataatgtttgggccacacatgcctgtgtaccca 5995  
env 64 D A K A Y D T E V H N V W A T H A C V P

Query: 5810 cagaccccaacccacaagaagtagtattggtaaattgtgacagaaaattttaacatgtgga 5869  
|||||

Sbjct: 5996 cagaccccaacccacaagaagtagtattggtaaattgtgacagaaaattttaacatgtgga 6055  
env 84 T D P N P Q E V V L V N V T E N F N M W

Query: 5870 aaaatgacatggtagaacagatgcatgaggatataatcagtttatgggatcaaagcctaa 5929  
|||||

Sbjct: 6056 aaaatgacatggtagaacagatgcatgaggatataatcagtttatgggatcaaagcctaa 6115  
env 104 K N D M V E Q M H E D I I S L W D Q S L

Query: 5930 agccatgtgtaaaattaaccccactctgtgttagtttaaagtgcactgatttgaagaatg 5989  
|||||

Sbjct: 6116 agccatgtgtaaaattaaccccactctgtgttagtttaaagtgcactgatttggggaatg 6175  
env 124 K P C V K L T P L C V S L K C T D L G N

Query: 5994 taataccaatagtagtagcggggagaatgataatggagaaaggagagataaaaaactgctc 6053  
|||||

Sbjct: 6195 taataccaatagtagtagcggggaaatgatgatggagaaaggagagataaaaaactgctc 6254  
env 151 N T N S S S G E M M M E K G E I K N C S

Query: 6054 tttcaatatcagcacaagcataagaggtaagggtgcagaaagaatatgcannnnnnnataa 6113  
|||||

Sbjct: 6255 tttcaatatcagcacaagcataagaggtaagggtgcagaaagaatatgcatttttttataa 6314  
env 171 F N I S T S I R G K V Q K E Y A F F Y K

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Query: 6114 acttgatataataaccaatagataatgatactaccagctatacggttgacaagttgtaacac 6173  
|||||  
Sbjct: 6315 acttgatataataaccaatagataatgatactaccagctatacggttgacaagttgtaacac 6374  
env 191 L D I I P I D N D T T S Y T L T S C N T

Query: 6174 ctcagtcattacacaggcctgtccaaaggtatcctttgagccaattcccatattattg 6233  
|||||  
Sbjct: 6375 ctcagtcattacacaggcctgtccaaaggtatcctttgagccaattcccatattattg 6434  
env 211 S V I T Q A C P K V S F E P I P I H Y C

Query: 6234 tgccccggctgggttttgcgattctaaaatgtaataataagacgttcaatggaacaggacc 6293  
|||||  
Sbjct: 6435 tgccccggctgggttttgcgattctaaaatgtaataataagacgttcaatggaacaggacc 6494  
env 231 A P A G F A I L K C N N K T F N G T G P

Query: 6294 atgtacaaatgtcagcacagtacaatgtacacatggaattaggccagtagtatcaactca 6353  
|||||  
Sbjct: 6495 atgtacaaatgtcagcacagtacaatgtacacatggaattaggccagtagtatcaactca 6554  
env 251 C T N V S T V Q C T H G I R P V V S T Q

Query: 6354 actgctgttaaatggcagctctggcagaagaagaggtagtaattagatctgccaatctcac 6413  
|||||  
Sbjct: 6555 actgctgttgaatggcagctctagcagaagaagaggtagtaattagatctgccaatctcac 6614  
env 271 L L L N G S L A E E E V V I R S A N F T

Query: 6414 agacaatgctaaaaccataatagtagcagctgaaccaatctgtagaaattaattgtacaag 6473  
|||||  
Sbjct: 6615 agacaatgctaaaaccataatagtagcagctgaaccaatctgtagaaattaattgtacaag 6674  
env 291 D N A K T I I V Q L N Q S V E I N C T R

Query: 6474 acccaacaacaataacaagaaaaagtatccgtatccagagaggaccaggaggagagcatttgt 6533  
|||||  
Sbjct: 6675 acccaacaacaataacaagaaaaagtatccgtatccagagaggaccaggaggagagcatttgt 6734  
env 311 P N N N T R K S I R I Q R G P G R A F V

Query: 6534 tacaataggaaaaataggaaatatgagacaagcacattgtaacattagtagagcaaaatg 6593  
|||||  
Sbjct: 6735 tacaataggaaaaataggaaatatgagacaagcacattgtaacattagtagagcaaaatg 6794  
env 331 T I G K I G N M R Q A H C N I S R A K W

Query: 6594 gaataacacttttaaacagatagatagcaaattaagagaacaatttggaataataaaaac 6653  
|||||  
Sbjct: 6795 gaatgccacttttaaacagatagctagcaaattaagagaacaatttggaataataaaaac 6854  
env 351 N A T L K Q I A S K L R E Q F G N N K T

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Query: 6654 aataatctttaagcagtcctcaggaggggacccagaaattgtaacgcacagttttaattg 6713  
|||||  
Sbjct: 6855 aataatctttaagcaatcctcaggaggggacccagaaattgtaacgcacagttttaattg 6914  
env 371 I I F K Q S S G G D P E I V T H S F N C

Query: 6714 tggaggggaatttttctactgtaattcaacacaactgtttaatagtacttggtttaatag 6773  
|||||  
Sbjct: 6915 tggaggggaatttttctactgtaattcaacacaactgtttaatagtacttggtttaatag 6974  
env 391 G G E F F Y C N S T Q L F N S T W F N S

Query: 6774 tacttggagtactaaaggggtcaaataacactgaaggaagtgcacacatcaccctcccatg 6833  
|||||  
Sbjct: 6975 tacttggagtactgaaggggtcaaataacactgaaggaagtgcacacatcacactcccatg 7034  
env 411 T W S T E G S N N T E G S D T I T L P C

Query: 6834 cagaataaaaacaattataaacatgtggcaggaagtaggaaaagcaatgtatgccctcc 6893  
|||||  
Sbjct: 7035 cagaataaaaacaattataaacatgtggcaggaagtaggaaaagcaatgtatgccctcc 7094  
env 431 R I K Q F I N M W Q E V G K A M Y A P P

Query: 6894 catcagtggaacaaattagatgttcatcaaatattacagggctgctattaacaagagatgg 6953  
|||||  
Sbjct: 7095 catcagcggaacaaattagatgttcatcaaatattacagggctgctattaacaagagatgg 7154  
env 451 I S G Q I R C S S N I T G L L L T R D G

Query: 6954 tggtaatagcaacaatgagtcagagatcttcagacctggaggaggagatatgagggacaa 7013  
|||||  
Sbjct: 7155 tggtaataacaacaatgggtccgagatcttcagacctggaggaggagatatgagggacaa 7214  
env 471 G N N N N G S E I F R P G G G D M R D N

Query: 7014 ttggagaagtgaattatataaatataaagtagtaaaaattgaaccattaggagtagcacc 7073  
|||||  
Sbjct: 7215 ttggagaagtgaattatataaatataaagtagtaaaaattgaaccattaggagtagcacc 7274  
env 491 W R S E L Y K Y K V V K I E P L G V A P

Query: 7074 caccaaggcaaagagaagagtgggtgcagagagaaaaaagagcagtggggaataggagcttt 7133  
|||||  
Sbjct: 7275 caccaaggcaaagagaagagtgggtgcagagagaaaaaagagcagtggggaataggagcttt 7334  
env 511 T K A K R R V V Q R E K R A V G I G A L

Query: 7134 gttccttgggttcttgggagcagcaggaagcactatgggagcagcgtaacgacgctgac 7193  
|||||  
Sbjct: 7335 gttccttgggttcttgggagcagcaggaagcactatgggagcagcgtaacgacgctgac 7394  
env 531 F L G F L G A A G S T M G A R S M T L T

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Query: 7194 ggtacaggccagacaattattgtctggtatagtgcagcagcagaacaatttgctgagggc 7253  
|||||  
Sbjct: 7395 ggtacaggccagacaattattgtctggtatagtgcagcagcagaacaatttgctgagggc 7454  
env 551 V Q A R Q L L S G I V Q Q Q N N L L R A

Query: 7254 tattgaggcgcaacagcatctgttgcaactcacagtctggggcatcaagcagctccaggc 7313  
|||||  
Sbjct: 7455 tattgaggcgcaacagcatctgttgcaactcacagtctggggcatcaagcagctccaggc 7514  
env 571 I E A Q Q H L L Q L T V W G I K Q L Q A

Query: 7314 aagaatcctggctgtggaaagatacctaaaggatcaacagctcctggggatttggggttg 7373  
|||||  
Sbjct: 7515 aagaatcctggctgtggaaagatacctaaaggatcaacagctcctgggnatttggggttg 7574  
env 591 R I L A V E R Y L K D Q Q L L G I W G C

Query: 7374 ctctggaaaactcatttgcaccactgctgtgccttggaatgctagttggagtaataaatc 7433  
|||||  
Sbjct: 7575 ctctggaaaactcatttgcaccactgctgtgccttggaatgctagttggagtaataaatc 7634  
env 611 S G K L I C T T A V P W N A S W S N K S

Query: 7434 tctggaacagatttggaataacatgacctggatggagtgggacagagaaattaacaatta 7493  
|||||  
Sbjct: 7635 tctggaacagatttggaataacatgacctggatggagtgggacagagaaattaacaatta 7694  
env 631 L E Q I W N N M T W M E W D R E I N N Y

Query: 7494 cacaagcttaatacactccttaattgaagaatcgcaaaaccagcaagaaaagaatgaaca 7553  
|||||  
Sbjct: 7695 cacaagcttaatacattccttaattgaagaatcgcaaaaccagcaagaaaagaatgaaca 7754  
env 651 T S L I H S L I E E S Q N Q Q E K N E Q

Query: 7554 agaattattggaattagataaatgggcaagtttggtggaattggtttaacataacaaattg 7613  
|||||  
Sbjct: 7755 agaattattggaattagataaatgggcaagtttggtggaattggtttaacataacaaattg 7814  
env 671 E L L E L D K W A S L W N W F N I T N W

Query: 7614 gctgtggtatataaaaattattcataatgatagtaggaggcttggttaggtttaagaatagt 7673  
|||||  
Sbjct: 7815 gctgtggtatataaaaattattcataatgatagtaggaggcttggttaggtttaagaatagt 7874  
env 691 L W Y I K I F I M I V G G L V G L R I V

Query: 7674 ttttgctgtactttctgtagtgaatagagtttaggcagggatattcaccattatcgtttca 7733  
|||||  
Sbjct: 7875 ttttgctgtactttctatagtgaatagagtttaggcagggatattcaccattatcgtttca 7934  
env 711 F A V L S I V N R V R Q G Y S P L S F Q

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Query: 7734 gacccacctcccaatcccgaggggacccgacaggcccgaaggaatagaagaagaagggtgg 7793  
|||||  
Sbjct: 7935 gacccacctcccaaccccgaggggacccgacaggcccgaaggaatagaagaagaagggtgg 7994  
env 731 T H L P T P R G P D R P E G I E E E G G

Query: 7794 agagagagacagagacagatccattcgattagtgaacggatccttagcacttatctggga 7853  
|||||  
Sbjct: 7995 agagagagacagagacagatccattcgattagtgaacggatccttagcacttatctggga 8054  
env 751 E R D R D R S I R L V N G S L A L I W D

Query: 7854 cgatctgcggagcctgtgcctcttcagctaccaccgcttgagagacttactcttgattgt 7913  
|||||  
Sbjct: 8055 cgatctgcggagcctgtgcctcttcagctaccaccgcttgagagacttactcttgattgt 8114  
env 771 D L R S L C L F S Y H R L R D L L L I V

Query: 7914 aacgaggattgtggaacttctgggacgcaggggggtgggaagccctcaaattattggtggaa 7973  
|||||  
Sbjct: 8115 aacgaggattgtggaacttctgggacgcaggggggtgggaagccctcaaattattggtggaa 8174  
env 791 T R I V E L L G R R G W E A L K Y W W N

Query: 7974 tctcctacagtattggagtcaggagctaaa  
|||||  
Sbjct: 8175 tctcctacagtattggagtcaggaactaaa  
env 811 L L Q Y W S Q E L K

It is noted that with regard to, for example, the sequence region claimed, there are 25 nucleotide differences between the sequences. It is noted that the art recognizes that sequencing errors occur in a range between 0.3 % and 2.5%, as evidenced by Richterich (Genome Research (1998) 8:251-259). However, these error rates are determined using technology that was significantly more advanced than that in 1984, when sequencing error rates were likely significantly higher. In the 2,462 nucleotide sequence which is the first sequence of claim 30, 25 errors would represent approximately a 1% error rate. Thus, these sequences are identical within the error range available and the anticipation rejection is proper.

***Response to Arguments***

5. Applicant's arguments filed March 7, 2003 have been fully considered but they are not persuasive.

First, Applicant will note the written description rejection, which addresses the absence of sequence attached to the "HIV LTR" phrase.

Second, Applicant argues that the current claims are distinguished from the Chang prior art because Chang expressly recognizes that part of the LTR sequence is not completely disclosed and the claims encompass that region. In particular, Applicant relies upon the specification of Chang, which notes at page 9 that "Because there are two SstI recognition sites within the LTR of HTLV-III DNA, one LTR region is not present in the cloned DNA sequence removed from the Lambda10 vector. As a result, a small (approximately 200 bp) fragment of the HTLV-III DNA is missing."

There are two separate problems with this argument. First, applicant has not shown which specific sequence was absent in Chang. HIV has two LTR regions, a 5' LTR and a 3' LTR. A review of genbank record K03455 demonstrates that the 5' LTR has the two Sst I sites discussed by Chang while the 3' LTR does not, thus indicating that Chang teaches a complete 3' LTR. Thus, to the extent that the claim requires a complete HIV LTR, Chang teaches a complete 3' LTR. Second, with regard to the sequences disclosed, none of these overlap or comprise the missing region in the 5' LTR. The 5' LTR region is shown below, with the two SstI sites underlined and in bold.

1 tggaagggct aattcactcc caacgaagac aagatatcct tgatctgtgg atctaccaca

61 cacaaggcta cttccctgat tagcagaact acacaccagg gccagggatc agatatccac

121 tgacctttgg atggtgctac aagctagtag cagttgagcc agagaagtta gaagaagcca  
181 acaaaggaga gaacaccagc ttgttacacc ctgtgagcct gcatggaatg gatgaccgg  
241 agagagaagt gttagagtgg aggtttgaca gccgcctagc attcatcac atggcccag  
301 agctgcatcc ggagtacttc aagaactgct gacatcgagc ttgtacaag ggactttccg  
361 ctggggactt tccagggagg cgtggcctgg gcgggactgg ggagtggcga gccctcagat  
421 cctgcatata agcagctgct tttgcctgt actgggtctc tctggttaga ccagatctga  
481 gcctgggagctctctggcta actaggggaac ccactgctta agcctcaata aagcttgct  
541 tgagtgttc aagtagtgtg tgcccgtctg ttgtgtgact ctggtaacta gagatccctc  
601 agaccctttt agtcagtgtg gaaaatctct agcagtggcg cccgaacagg gacctgaaag  
661 cgaaagggaa accagaggagctc

So it is this region between nucleotides 486 and 682 which is missing in Chang, according to Chang. None of applicant's claims are drawn to this region in any specific way, and since Chang teaches a complete 3' HIV LTR, Chang continues to meet the limitations of the claim.

### **Conclusion**

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is 703-308-6568. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jeffrey Fredman  
Primary Examiner  
Art Unit 1634

April 30, 2003